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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,427	03/22/2000	John A. Chiorini	14014.0323U2	8626

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	16

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/533,427	Applicant(s) CHIORINI ET AL.	
	Examiner Anne Falk	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

The response filed January 29, 2002 (Paper No. 10) has been entered.

Claims 1-11 are pending in the instant application.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See the correction to the address for Robert Kotin.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method of delivering a nucleic acid, wherein intranasal administration of AAV5 particles is used to deliver the nucleic acid to an alveolar cell and direct injection into the brain is used to deliver a nucleic acid to a cerebellar cell or an ependymal cell, does not reasonably provide enablement for the claimed methods, wherein another mode of administration is employed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For reasons of record advanced on pages 2-5 of the Office Action of Paper No. 6 (mailed 7/5/01), the specification is not broadly enabling for varying modes of administration. The specification fails to provide an enabling disclosure for targeting appropriate cells for *in vivo* applications of the claimed method. Only general guidance is offered for targeting strategies known in the art. However, the art recognizes that targeting strategies are not currently sufficient to overcome the problems known in the art. See especially the discussion at pages 4-5 of the Office Action of Paper No. 6. The claims broadly encompass any mode of administration for delivering a nucleic acid to a cerebellar cell, an ependymal cell, and an alveolar cell, but the specification does not broadly enable any mode of administration. For example, the specification does not enable intravenous or intraarterial administration to deliver a nucleic acid to a cerebellar cell, an ependymal cell, or an alveolar cell.

In view of the limited guidance in the specification, the broad scope of the claims, the limited working examples for *in vivo* gene delivery, and the unpredictability in the art of gene delivery, undue experimentation would have been required for one skilled in the art to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in its recitation of "wherein the cell selected from the group consisting of:" because the phrase is not grammatically correct and is therefore confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 6, 7, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,309,634 (Bankiewicz et al.).

The claims are directed to a method of delivering a nucleic acid to a cell by administering an AAV5 particle containing a nucleic acid inserted between a pair of AAV inverted terminal repeats. Claims 2, 7 and 10 are specifically directed to delivering a nucleic acid to a cell in a subject.

Bankiewicz et al. disclose a method for treating Parkinson's disease in a subject by administering recombinant AAV virions to brain cells. See Claim 1. The specification explicitly states that AAV-5 vectors may be used in the invention (Column 12, lines 41-45). Furthermore, the specification explicitly states that the AAV ITR may be derived from AAV-5 (Column 13, lines 14-17).

Thus, the claimed method is disclosed in the prior art.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,391,858 (Podsakoff et al.).

The claims are directed to a method of delivering a nucleic acid to a cell by administering an AAV5 particle containing a nucleic acid inserted between a pair of AAV inverted terminal repeats. Claim 2 is specifically directed to delivering a nucleic acid to a cell in a subject.

Podsakoff et al. disclose a method of administering a recombinant AAV virion to a mammalian subject. See Claim 1. The specification explicitly states that AAV-5 vectors may be used in the invention (Column 6, lines 50-52). Furthermore, the specification explicitly states that the AAV ITR may be derived from AAV-5 (Column 10, lines 22-24).

Thus, the claimed method is disclosed in the prior art.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,221,349 (Couto et al.).

The claims are directed to a method of delivering a nucleic acid to a cell by administering an AAV5 particle containing a nucleic acid inserted between a pair of AAV inverted terminal repeats. Claim 2 is specifically directed to delivering a nucleic acid to a cell in a subject.

Couto et al. disclose a method of delivering a nucleotide sequence to a mammal by administering a recombinant AAV virion to the mammal. See Claim 1. The specification explicitly states that AAV-5 vectors may be used in the invention (Column 6, lines 16-20 and Column 12, lines 25-27). Furthermore, the specification explicitly states that the AAV ITR may be derived from AAV-5 (Column 12, lines 54-57).

Thus, the claimed method is disclosed in the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,180,613 (Kaplitt et al., filed June 6, 1995) and Georg-Fries et al. (1984).

The claims are directed to a method of delivering a nucleic acid to a cell by administering an AAV5 particle containing a nucleic acid inserted between a pair of AAV inverted terminal repeats. Claims 2, 7 and 10 are specifically directed to delivering a nucleic acid to a cell in a subject.

Kaplitt et al. disclose a method for ameliorating a symptom of a central nervous system disorder in a mammal by administering an AAV vector to a target cell in the brain of the mammal. See Claim 1. Claim 11 specifically recites that the target cell is in the cerebellum. The specification and the claims read broadly on AAV vectors of any subtype, including AAV-5.

Georg-Fries et al. (1984) disclose that the type 5 adeno-associated virus has been known in the art since 1984.

Since AAV5 has been known in the art since 1984 and further since the claims of Kaplitt et al. read broadly on AAV vectors of any subtype, it is evident that in 1995 Kaplitt contemplated using AAV5 vectors, as well as AAV vectors of other subtypes, in practicing the claimed methods.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE BAKER
PATENT EXAMINER